

The Department of Health and Human Services
Meeting of the
Secretary's Advisory Committee on Human Research Protections (SACHRP)
Monday, January 31, 2005 – Tuesday, February 1, 2005
The Radisson Hotel Old Town Alexandria
901 North Fairfax Street
Alexandria, VA

DRAFT AGENDA

Monday, 31 January 2005

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|-----------------------|--|
| 8:30 am – 8:35 am | Welcome: Opening Remarks
Ernest Prentice, Ph.D.
Chairman, SACHRP |
| 8:35 am – 8:45 am | Report of Issues
Bernard Schwetz, D.V.M., Ph.D.
Director, OHRP |
| 8:45 am – 9:00 am | Overview of Charges to Subcommittees
Approval of Minutes from October 4, 5 meeting
Ernest Prentice, Ph.D.
Chairman, SACHRP |
| 9:00 am – 9:30 am | Public Comment |
| 9:30 am – 10:30 am | Report of Subcommittee on Research Involving
Children
Celia Fisher, Ph.D., Co-Chair
Susan Kornetsky, M.P.H., Co-Chair |
| 10:30 am – 10:45 am | BREAK |
| 10:45 am – 12:00 noon | Report of Subcommittee on Research Involving
Children |
| 12:00 noon – 1:00 pm | LUNCH |
| 1:00 pm – 3:00 pm | Report on Subpart C Subcommittee on Research
Involving Prisoners
Mark Barnes, J.D., L.L.M., Co-Chair
Nancy Dubler, L.L.M., Co-Chair |
| 3:00 pm – 3:15 pm | BREAK |

3:15 pm – 4:00 pm

Report on Subpart C Subcommittee on Research
Involving Prisoners

4:00 pm – 4:30 pm

Public Comment

4:30 pm – 5:00 pm

Discussion of committee business/adjourn

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Tuesday, February 1

8:30 am – 8:45 am	Additional Business Ernest Prentice, Ph.D. Chairman, SACHRP
8:45 am – 10:15 am	Adverse Events issues Update and discussion Amy Patterson, M.D, NIH Jean-Louis Saillot, M.D, Schering-Plough Research Institute
10:15 am – 10:30 am	BREAK
10:30 am – 11:30 am	Subpart A presentation and future plans Felix Gyi, Pharm D, M.B.A., CIP, Co-Chair Daniel Nelson, M.S., CIP, Co-Chair
11:30 am – 12:00 pm	Public Comment
12:00 pm – 1:00 pm	LUNCH
1:00 pm -- 3:00 pm	Discussion of Compliance Oversight Activities Kristina Borrer, Ph.D., Director, Compliance Division, OHRP Joanne Rhoads, M.D, M.P.H., FDA Michael Klag, M.D, Johns Hopkins University Thomas Puglisi, Ph.D., CIP, PriceWaterhouse Coopers

Chris Pascal, J.D.
Director, Office of Research Integrity,
DHHS

3:00 pm – 3:15 pm

BREAK

3:15 pm – 4:00 pm

Discussion of Committee business/adjourn